No. 801

In the Supreme Court of the United States

OCTOBER TERM, 1944

ARNER COMPANY, INC., ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

INDEX

CITATIONS

605729—44——1

In the Supreme Court of the United States

OCTOBER TERM, 1944

No. 301

ARNER COMPANY, INC., ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the circuit court of appeals (R. 20–33) is reported at 142 F. (2d) 730. The memorandum of decision of the district court appears at pages 8–9 of the Record.

JURISDICTION

The judgment of the circuit court of appeals was entered May 4, 1944 (R. 33). The petition for a writ of certiorari was filed July 29, 1944. The jurisdiction of this Court is invoked under Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925.

QUESTIONS PRESENTED

1. Whether shipments in bulk of drugs intended to be processed and labeled before sale to the consumer are *ipso facto* exempt from the labeling requirements of the Federal Food, Drug, and Cosmetic Act.

2. Whether the Federal Security Administrator was authorized to promulgate a regulation requiring as a condition for the exemption of bulk shipments from the labeling requirements of the Act, that the shipper and the processor enter into a written agreement containing specifications for the processing, labeling, or repacking of the final product.

3. Whether a manufacturing agent who prepares drugs in accordance with a formula owned by the processor and sends such drugs to the processor in bulk form is a person introducing the bulk shipment into interstate commerce.

STATUTE AND REGULATIONS INVOLVED

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. 301 ff, are as follows:

> SEC. 201 (21 U. S. C. 321). For the purposes of this Act—
>
> * * * * *
>
> (k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or

other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

* * * * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

* * * * *

SEC. 304 (a) (21 U. S. C. 334 (a)). Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: * * *.

* * * * *

SEC. 502 (21 U. S. C. 352). A drug or device shall be deemed to be misbranded—

* * * * *

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such

there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein * * *.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided,* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement.

* * * * *

SEC. 503 (a) (21 U. S. C. 353 (a)). The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of

this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

The pertinent regulations promulgated by the Administrator pursuant to Section 503 (a) (21 C. F. R. 1938 Supp., 2.107) are as follows:

(a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501 (b) and 502 (b), (d), (e), (f), and (g) of the Act if—

(1) the person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or

(2) in case such person is not such operator, such shipment or delivery is made to

such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

STATEMENT

A libel was filed in the United States District Court for the District of Massachusetts seeking the condemnation of certain drugs shipped by Arner Company, Inc., from Buffalo, New York, to Paul Case at Brockton, Massachusetts, on the ground that the drugs were misbranded within the meaning of the Federal Food, Drug and Cosmetic Act in that the labels failed to bear the common names of the active ingredients, and contained no directions for use of the drugs and no warnings against use under conditions that might be dangerous to

health (R. 2–3). Petitioners filed separate answers to the libel (R. 3–5). The cause was heard on the pleadings and on an agreed statement of facts (R. 10–11), and on April 6, 1943, the district court entered a decree of forfeiture (R. 7). On appeal, the decree of the district court was affirmed (R. 33).

The material facts, as set forth in the agreed statement, are as follows:

The drugs seized under the libel consisted of a drum containing about 40,000 tablets which had been manufactured in Buffalo, New York, by petitioner Arner Company, Inc., for petitioner Paul Case under a special formula owned by Case. They had been shipped f. o. b. Buffalo by Arner to Case at Brockton, Massachusetts. At the time they were seized they were in Case's establishment in the bulk package in which they had been shipped (R. 10–11, 14). The drum was labeled "Special Formula Tablets No. 2 * * * —The product contained herein must be packaged and labeled at point of destination before sale" (R. 13). On April 28, 1939, prior to the shipment in question, Case had delivered to Arner a letter guaranteeing "that each shipment or other delivery hereinafter made of the drug known or designed as my Formula No. 1 and Formula No. 2, is not adulterated or misbranded, as of the date of such shipment or delivery, within the meaning of the Federal Food, Drug and Cosmetic

Act, and is not an article which may not under the provisions of Section 505 [21 U. S. C. 355] of the Act, be introduced into commerce" (R. 10, 15). Arner was not the operator of the establishment at which the drugs were to be repackaged and labeled for the retail trade (R. 10).

ARGUMENT

1. Petitioners contend (Pet. 8, 9, 13–23) that under the definition of "label" set forth in Section 201 (k) of the Act (*supra*, pp. 2–3), shipments in bulk of drugs which are intended for repackaging and labeling before they reach the ultimate consumer need not under any circumstances be labeled in compliance with the requirements of Section 502. However, "label" is broadly defined in Section 201 (k) as "a display of written, printed, or graphic matter upon *the immediate container of any article.*" (Italics supplied.) No distinction is made between articles in bulk and articles packed for retail sale. In addition, "labeling" is defined in Section 201 (m) (*supra*, p. 3) as including "all labels and other written, printed, or graphic matter (1) upon *any* article or *any* of its containers or wrappers * * *." (Italics supplied.) The second clause of Section 201 (k), specifically referring to retail packages and requiring an additional statement on the outside container or wrapper, as well as on the immediate container, is obviously an extension, and not a limitation, of the

general definition. That Congress intended that bulk shipments, unless exempted, shall be labeled in compliance with the Act is shown by the fact that it found it necessary to direct the Administrator to promulgate regulations providing for the exemption from the labeling requirements of drugs and devices which are, in accordance with the practice of the trade, to be processed, repacked, or labeled at establishments other than those where they are originally processed or packed (Sec. 503 (a), *supra,* pp. 4–5). As the court below pointed out (R. 23), if bulk shipments were not subjected to the labeling requirements under the general definition, there would have been no need for the exemption provision.

McDermott v. *Wisconsin*, 228 U. S. 115, cited by petitioners (Pet. 14), which defined the term "package" as used in the Federal Food and Drugs Act of 1906 (34 Stat. 768) as "the immediate container of the article which is intended for consumption by the public" (228 U. S. at 130), is not apposite. In that case the principal issue concerned the validity of a state statute regulating labels on retail packages in view of its possible conflict with the Federal act, and the resolution of that issue turned on the question whether the requirements of the 1906 act extended to labels on the immediate containers of retail packages or were confined in their application to the outside wrapping or box in which such packages were shipped. Unlike the present statute, the 1906

act contained no definitions of "label" and "labeling" and no provision for the exemption of bulk shipments intended to be repacked and labeled. This Court held that that act covered retail packages; that to limit "the requirements of the act as to adulteration and misbranding simply to the outside wrapping or box containing the packages intended to be purchased by the consumer, so that the importer, by removing and destroying such covering, could prevent the operation of the law on the imported article yet unsold, would render the act nugatory and its provisions wholly inadequate to accomplish the purposes for which it was passed" (228 U. S. at 130–131).[1] The Court did not have before it and did not determine the question whether labeling was required on a bulk shipment which contained no retail packages. Hence, the decision and language of the Court in the *McDermott* case furnish no support for petitioners' contention that the labeling requirements of the present statute do not extend to such shipments.[2]

---

[1] *Dr. J. L. Stephens Co.* v. *United States*, 203 Fed. 817 (C. C. A. 6), also cited by petitioners (Pet. 21), involved a similar question as to the labeling under the 1906 act of retail packages.

[2] The decision in *United States* v. *Knowlton Danderine Co.*, 175 Fed. 1022 (C. C. A. 4), relied upon by petitioners as presenting a conflict with the decision below (Pet. 9, 20–21, 26), turned upon different considerations than those urged by petitioners here. The lower court had held in that case that a shipment of drugs from the manufacturing agent to the owner was not a shipment in interstate commerce. *United*

2. Petitioners also contend (Pet. 23–26, 28–34) that under Section 503 (a) of the present act, which directs the Administrator to promulgate regulations exempting from the labeling requirements of the act drugs which are to be processed, labeled, or repacked at establishments other than those where originally processed on condition that such drugs are not adulterated or misbranded

---

States v. *Sixty-five Casks Liquid Extract*, 170 Fed. 449 (N. D. W. Va.). In affirming the order dismissing the libel, the circuit court of appeals held that the casks were not subject to the 1906 act because they "were not intended for sale as shipped." 175 Fed. at 1022. Section 10 of the 1906 act (34 Stat. 771) provided for the seizure of adulterated or misbranded articles "being transported from one State * * * to another for sale," and there was thus some justification for a holding that goods transported for further processing were not transported for sale. This Court held, however, in *Hippolite Egg Co.* v. *United States*, 220 U. S. 45, that adulterated foods shipped by the owner from one state to another for further processing were subject to the 1906 act (see also *Strong, Cobb & Co.* v. *United States*, 103 F. (2d) 671, 673 (C. C. A. 6), *Philadelphia Pickling Co.* v. *United States*, 202 Fed. 150 (C. C. A. 3)), and its holding in this respect was interpreted as overruling the *Knowlton* decision in respect of misbranded goods as well. *United States* v. *426 Bags of Economy Special Hog Feed*, 276 Fed. 34 (W. D. Mich.). But regardless of the authoritativeness of the *Knowlton* case under the 1906 act, it has no controlling force here, for Section 304 of the present act (*supra*, p. 3) omits the words "for sale" and provides for the seizure of any misbranded or adulterated article "when introduced into or while in interstate commerce." Petitioners admit (Pet. 34) that the shipment here involved was a shipment in interstate commerce. Cf. *Santa Cruz Fruit Packing Co.* v. *National Labor Relations Board*, 303 U. S. 453, 463; *Barnes* v. *United States*, 142 F. (2d) 648, 650 (C. C. A. 9).

upon removal from such repacking establishments (*supra*, pp. 4–5), regulations issued by the Administrator must be directed to the operator of the repacking establishment and must affirmatively provide for the exemption of bulk shipments subject only to the condition that the drugs be not misbranded when removed from such establishment for sale to the public. There is no warrant for such a narrow construction of Section 503 (a). The section clearly expresses an intention to relieve bulk shipments from the labeling requirements only under conditions which will insure that the drugs are properly labeled when sold to the public. The fact that the ultimate purpose is to protect the consumer does not, however, preclude reasonable regulations directed to the shipper, as well as the processor, which are designed to further that object. The regulations promulgated by the Administrator are valid if they fulfill the purpose of the statute, *United States* v. *Antikamnia Co.*, 231 U. S. 654, 667, and his judgment as to the conditions which will facilitate that purpose are entitled to great weight. Cf. *Security Administrator* v. *Quaker Oats Co.*, 318 U. S. 218, 228.

Paragraph (a) (2) of the regulations here involved, which requires, as a condition for the exemption of bulk shipments, that the shipper and the processor enter into a written agreement containing specifications for the labeling of the drugs as sold to the consumer (*supra*, pp. 5–6),

is clearly designed to effectuate not only the objectives of the statute as a whole, but also the particular condition set forth in Section 503 (a) that the finished product shall comply with the statutory standards. The regulation merely requires both parties who are responsible for the finished product to state in writing that they propose to do what the act requires them to do, and to state their purpose in terms explicit enough to show good faith. The person who manufactures and ships the drugs in bulk knows what the product contains and how it should be labeled. He may label the bulk shipment itself, or he may avoid the labeling requirements by agreeing with the processor as to the correct labeling. In either event he would be indicating, when he uses the instrumentalities of interstate commerce for the shipment of the drugs, that they are to be properly labeled when sold to the ultimate consumer.[3] Moreover, as the court below pointed out (R. 27–28, 32), the requirement that bulk shipments be properly labeled or that the specifications for labeling be specifically set forth in a written agreement facilitates the administration of the act in

[3] Petitioners' contention (Pet. 28–29) that the regulation is invalid because it imposed a requirement different from that set forth in Section 303 (c) (2), 21 U. S. C. 333 (c), exempting consignees from criminal prosecution if they receive a guarantee from the shipper, is specious. Section 303 (c) (2) applies to the person who receives the drugs from another, not to the person who first ships the drugs. Cf. *United States* v. *Dotterweich*, 320 U. S. 277.

that the federal authorities may ascertain at an early stage whether drugs shipped in bulk form will actually meet the statutory standards when repacked and labeled for sale to the consumer.

3. There is no merit in petitioner's further contention (Pet. 26–27) that, since title to the drugs passed to petitioner Case upon their shipment from New York to Massachusetts, the shipment is covered by paragraph (a) (1) of the regulations, which exempts from the labeling requirements of the act drugs introduced into interstate commerce by a shipper who is also the operator of the establishment at which the drugs are to be repacked or labeled (*supra,* p. 5). Arner Company, which admittedly is not the operator of the establishment at which the drugs were to be repacked, actually shipped the drugs, and was therefore the "person" who introduced the shipment into interstate commerce. The obvious purpose of paragraph (a) (1) of the regulations is to distinguish between situations where the person who manufactures and ships the bulk article is the one who processes it for the retail trade, and situations where one person ships the bulk product and another processes it. In the first instance one person is responsible for the whole operation; in the other there is the possibility that each of the two persons involved will try to shift responsibility to the other, a situation which paragraph (a) (2) of the regulations is intended to prevent. It may be, as petitioners contend (Pet.

27), that the shipment would have been within the scope of paragraph (a) (1) if Case had himself shipped the bulk package from Buffalo to Brockton but, in that event Arner Company would not have been using the instrumentalities of interstate commerce and therefore would not have come within the purview of the act. The fact that the act does not apply to manufacturers who do not send their products through interstate commerce does not prevent the Administrator from issuing reasonable regulations to cover situations where they do. The technicalities of the law of sales as to the passage of title do not alter the interstate character of the transaction and cannot be used to avoid responsibility under the act. *Barnes* v. *United States,* 142 F. (2d) 648, 650 (C. C. A. 9).

CONCLUSION

The decision below is correct and presents no real conflict of decisions. We therefore respectfully submit that the petition for a writ of certiorari should be denied.

CHARLES FAHY,
Solicitor General.

TOM C. CLARK,
Assistant Attorney General.

ROBERT S. ERDAHL,
Special Assistant to the Attorney General.

BEATRICE ROSENBERG,
Attorney.

AUGUST 1944.

U. S. GOVERNMENT PRINTING OFFICE: 1944